

**§ 172.872**

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(2) The additive identified in paragraph (a)(2) of this section is used or intended for use as a binder and disintegrator in tablets or wafers containing dietary supplements of vitamins and/or minerals. The additive is used in accordance with good manufacturing practice.

[46 FR 50065, Oct. 9, 1981]

**§ 172.872 Methyl ethyl cellulose.**

The food additive methyl ethyl cellulose may be safely used in food in accordance with the following prescribed conditions.

(a) The additive is a cellulose ether having the general formula  $[C_6H_{(10-x-y)}O_5(CH_3)_x(C_2H_5)_y]_n$ , where  $x$  is the number of methyl groups and  $y$  is the number of ethyl groups. The average value of  $x$  is 0.3 and the average value of  $y$  is 0.7.

(b) The additive meets the following specifications:

(1) The methoxy content shall be not less than 3.5 percent and not more than 6.5 percent, calculated as  $OCH_3$ , and the ethoxy content shall be not less than 14.5 percent and not more than 19 percent, calculated as  $OC_2H_5$ , both measured on the dry sample.

(2) The viscosity of an aqueous solution, 2.5 grams of the material in 100 milliliters of water, at 20 °C, is 20 to 60 centipoises.

(3) The ash content on a dry basis has a maximum of 0.6 percent.

(c) The food additive is used as an aerating, emulsifying, and foaming agent, in an amount not in excess of that reasonably required to produce its intended effect.

**§ 172.874 Hydroxypropyl methylcellulose.**

The food additive hydroxypropyl methylcellulose (CAS Reg. No. 9004-65-3) may be safely used in food, except in standardized foods which do not provide for such use if:

**21 CFR Ch. I (4-1-01 Edition)**

(a) The additive complies with the definition and specifications prescribed in the National Formulary, 12th edition.

(b) It is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(c) To insure safe use of the additive, the container of the additive, in addition to being labeled as required by the general provisions of the act, shall be accompanied by labeling which contains adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 38273, Aug. 31, 1982]

**§ 172.876 Castor oil.**

The food additive castor oil may be safely used in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia XX (1980).

(b) The additive is used or intended for use as follows:

*Use and Limitations*

Hard candy production—As a release agent and antisticking agent, not to exceed 500 parts per million in hard candy.

Vitamin and mineral tablets—As a component of protective coatings.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

**§ 172.878 White mineral oil.**

White mineral oil may be safely used in food in accordance with the following conditions:

(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum. It is refined to meet the following specifications:

(1) It meets the test requirements of the United States Pharmacopeia XX (1980) for readily carbonizable substances (page 532).

(2) It meets the test requirements of U.S.P. XVII for sulfur compounds (page 400).

(3) It meets the specifications prescribed in the "Journal of the Association of Official Analytical Chemists,"